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Title: "Immunotherapeutic Methods Using Epitopes of WT-1 and GATA-1"  
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**Preliminary Amendment**  
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original claims. A copy of all of the pending claims as they are believed to have been amended is attached to this Preliminary Amendment as an appendix.

Applicants respectfully request allowance of claims 1, 4-20, and 22-38.

Respectfully submitted,



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### Appendix: Claims as Pending after Amendment

1. (Amended) A peptide comprising the amino acid sequence RMFPNAPYL (SEQ ID NO:1), the amino acid sequence CMTWNQMNL (SEQ ID NO:2), the amino acid sequence HLMPFPGPLL (SEQ ID NO:3), or a portion or variant thereof provided that the peptide is not intact human WT-1 polypeptide and is not intact human gata-1 polypeptide.
4. (Amended) A peptide according to [any one of Claims 1 to 3] Claim 1 wherein the peptide is capable of binding to HLA-A0201.
5. (Unamended) A peptide according to Claim 4 wherein when bound to HLA-A0201 the peptide-bound HLA-A0201 is capable of eliciting the production of a cytotoxic T lymphocyte (CTL) which recognises a cell which aberrantly expresses a polypeptide comprising the given amino acid sequence.
6. (Amended) A peptide according to [any one of Claims 1 to 5] Claim 1 wherein the peptide includes non-peptide bonds.
7. (Amended) A peptide according to Claim 1 consisting of the amino acid sequence RMFPNAPYL (SEQ ID NO:1).
8. (Amended) A peptide according to Claim 1 consisting of the amino acid sequence CMTWNQMNL (SEQ ID NO:2).
9. (Amended) A peptide according to Claim 1 consisting of the amino acid sequence HLMPFPGPLL (SEQ ID NO:3).
10. (Amended) A polynucleotide encoding a peptide according to [anyone of Claims 1 to 5 and 7 to 9] Claim 1.
11. (Amended) A polynucleotide according to Claim 10 which is DNA.
12. (Amended) An expression vector capable of expressing a [polypeptide] peptide according to [any one of Claim 1 to 5 and 7 to 9] Claim 1.

13. (Amended) A host cell comprising a polynucleotide [according to Claim 10 or 11] encoding a peptide according to Claim 1, or an expression vector [according to Claim 12] capable of expressing the peptide.

14. (Amended) A method of producing a peptide, [according to any one of Claims 1 to 5 and 7 to 9] the method comprising culturing the host cell according to Claim 13 and obtaining the peptide from the host cell or its culture medium.

15. (Amended) A pharmaceutical composition comprising a peptide according to [any one of Claims 1 to 9] Claim 1 and a pharmaceutically acceptable carrier.

16. (Amended) A pharmaceutical composition comprising a polynucleotide [according to Claim 10 or 11] encoding a peptide according to Claim 1, or an expression vector [according to Claim 12] capable of expressing the peptide, and a pharmaceutically acceptable carrier.

17. (Amended) A method of treating a patient, the method comprising administering a peptide according to [any one of Claims 1 to 9 for use in medicine] Claim 1 to a patient.

18. (Amended) A method of treating a patient, the method comprising administering a polynucleotide [according to Claim 10 or 11] encoding a peptide according to Claim 1, or an expression vector [according to Claim 12 for use in medicine] capable of expressing the peptide, to a patient.

19. (Amended) A cancer vaccine comprising a peptide according to [any one of Claims 1 to 9 or] Claim 1, a polynucleotide [according to Claim 10 or 11] encoding the peptide, or an expression vector [according to Claim 12] capable of expressing the peptide.

20. (Amended) A method of killing target cells in a patient, which target cells aberrantly express a polypeptide comprising [an] the amino acid sequence [given in any of Claims 1 to 3] RMFPNAPYL (SEQ ID NO:1), the amino acid sequence CMTWNQMNL (SEQ ID NO:2), or the amino acid sequence HLMPPFGPLL (SEQ ID NO:3), the method comprising administering to the patient an effective amount of a peptide according to [any one of Claims 1 to 9 or] Claim

1, a polynucleotide [according to Claim 10 or 11] encoding the peptide, or an expression vector [according to Claim 12] capable of expressing the peptide wherein the amount of said peptide or amount of said polynucleotide or amount of said expression vector is effective to provoke an anti-target cell immune response in said patient.

22. (Amended) A method for producing activated cytotoxic T lymphocytes (CTL) *in vitro*, the method comprising contacting *in vitro* CTL with antigen-loaded human class I MHC molecules expressed on the surface of a suitable antigen-presenting cell for a period of time sufficient to activate, in an antigen specific manner, [said] the CTL wherein the antigen is a peptide according to [any one of Claims 1 to 9] Claim 1.

23. (Unamended) A method according to Claim 22 wherein the CTL and the antigen-presenting cell are allogeneic (allorestricted) with respect to the class I MHC molecule.

24. (Unamended) A method according to Claim 22 wherein the CTL and the antigen-presenting cell are syngeneic (self-restricted) with respect to the class I MHC molecule.

25. (Amended) A method according to [any one of Claims 22 to 24] Claim 22 wherein the antigen is loaded onto class I MHC molecules expressed on the surface of a suitable antigen-presenting cell by contacting a sufficient amount of the antigen with an antigen-presenting cell wherein before contact the class I MHC molecules of the antigen-presenting cell are substantially unoccupied and after contact the class I MHC molecules are substantially fully occupied.

26. (Amended) A method according to [any of Claims 22 to 24] Claim 22 wherein the antigen-presenting cell comprises an expression vector [according to Claim 12] capable of encoding a peptide comprising the amino acid sequence RMFPNAPYL (SEQ ID NO:1), the amino acid sequence CMTWNQMNL (SEQ ID NO:2), the amino acid sequence HLMFPFGPLL (SEQ ID NO:3), or a portion or variant thereof provided that the peptide is not intact human WT-1 polypeptide and is not intact human gata-1 polypeptide.

27. (Amended) A method according to [any one of Claims 22 to 26] Claim 22 wherein the class I MHC molecule is HLA-A0201.

28. (Amended) Activated cytotoxic T lymphocytes (CTL) obtainable by the method according to [any one of Claims 22 to 27] Claim 22.

29. (Amended) Activated cytotoxic T lymphocytes (CTL) which selectively recognise a cell which aberrantly expresses a polypeptide comprising an amino acid sequence given in [any one of Claims 1 to 3] Claim 1.

30. (Amended) A T-cell receptor (TCR) which recognises a cell which aberrantly expresses a polypeptide comprising [an] the amino acid sequence [given in any one of Claims 1 to 3] RMFPNAPYL (SEQ ID NO:1), the amino acid sequence CMTWNQMNL (SEQ ID NO:2), or the amino acid sequence HLMPFPGPLL (SEQ ID NO:3), the TCR being obtainable from the cytotoxic T lymphocyte (CTL) [of Claims 28 or 29] obtainable by the method according to Claim 22, or a functionally equivalent molecule to the TCR.

31. (Unamended) A polynucleotide encoding a T cell receptor (TCR) as defined in Claim 30.

32. (Unamended) An expression vector capable of expressing a T cell receptor (TCR) as defined in Claim 30.

33. (Amended) A method of killing target cells in a patient which target cells aberrantly express a polypeptide comprising [an] the amino acid sequence [given in any one of Claims 1 to 3] RMFPNAPYL (SEQ ID NO:1), the amino acid sequence CMTWNQMNL (SEQ ID NO:2), or the amino acid sequence HLMPFPGPLL (SEQ ID NO:3), the method comprising administering to the patient an effective number of cytotoxic T lymphocytes (CTL) as defined in [Claims 28 or 29] Claim 28.

34. (Amended) A method of killing target cells in a patient, which target cells aberrantly express a polypeptide comprising [an] the amino acid sequence [given in any one of Claims 1 to

3] RMFPNAPYL (SEQ ID NO:1), the amino acid sequence CMTWNQMNL (SEQ ID NO:2), or the amino acid sequence HLMPFPGPLL (SEQ ID NO:3), the method comprising the steps of (1) obtaining cytotoxic T lymphocytes (CTL) from the patient; (2) introducing into [said] the cells a polynucleotide encoding a T cell receptor (TCR), or a functionally equivalent molecule, as defined in Claim 30; (3) introducing the cells produced in step (2) into the patient.

35. (Amended) A method of killing target cells in a patient which target cells aberrantly express a polypeptide comprising [an] the amino acid sequence [given in any one of Claims 1 to 3] RMFPNAPYL (SEQ ID NO:1), the amino acid sequence CMTWNQMNL (SEQ ID NO:2), or the amino acid sequence HLMPFPGPLL (SEQ ID NO:3), the method comprising the steps of (1) obtaining dendritic cells from said patient; (2) contacting said dendritic cells with a peptide as defined in [any one of Claims 1 to 9 or which] Claim 1, with a polynucleotide encoding the peptide, or with an expression vector [according to Claim 10 to 12] capable of expressing the peptide ex vivo; and (3) reintroducing the so treated dendritic cells into the patient.

36. (Amended) A method of killing target cells in a patient according to [any one of] Claim 20 [or 33 to 35] wherein the target cells are cancer cells.

37. A method according to Claim 36 wherein the cancer is any one of a leukaemia, breast cancer, melanoma and ovarian cancer which aberrantly expresses the WT1 polypeptide which comprises the amino acid sequences RMFPNAPYL (SEQ ID NO:1) and CMTWNQMNL (SEQ ID NO:2).

38. A method according to Claim 36 wherein the cancer is a leukaemia which aberrantly expresses the gata-1 polypeptide which comprises the amino acid sequence HLMPFPGPLL (SEQ ID NO:3).